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Date of Deposit: March 17, 2004  
Docket No. M0656.70070US00

1623

DOCKET NO.: M0656.70070US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Liu et al.  
Serial No: 09/982,548  
Confirmation. No.: 7782  
Filed: October 18, 2001  
For: METHODS AND PRODUCTS RELATED TO PULMONARY  
DELIVERY OF POLYSACCHARIDES  
Examiner: McIntosh III, Traviss C.  
Art Unit: 1623

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

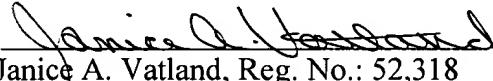
Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Check in the amount of \$180.00
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180.00 is enclosed. If a further fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Liu et al., Applicant*

By:   
Janice A. Vatland, Reg. No.: 52,318  
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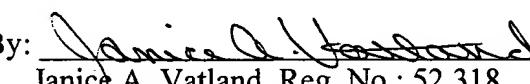
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P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

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03/19/2004 EFLORES 00000022 09982548

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The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
M0656.70055WO00	PCT/US00/10990	04/24/2000	Venkataraman et al.
M0656.70076US00	10/108,195	03/27/2002	Kwan et al.
M0656.70086US00	10/291,337	11/08/2002	Liu et al.
M0656.70089US00	10/356,349	01/31/2003	Venkataraman et al.
M0656.70089US01	10/760,133	01/16/2004	Venkataraman et al.
M0656.70089US02	10/759,520	01/16/2004	Venkataraman et al.
M0656.70092US00	10/429,921	05/05/2003	Myette et al.
M0656.70094US00	10/441,970	05/20/2003	Sasisekharan et al.
M0656.70095US00	10/454,816	06/03/2003	Pojasek et al.
M0656.70096US00	10/753,761	01/07/2004	Sasisekharan et al.

The Applicant would like to bring to the Examiner's attention the enclosed search reports from the corresponding International Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Report</u>
M0656.70070WO00	PCT/US01/32444	August 20, 2002	International Search Report
M0656.70070WO00	PCT/US01/32444	March 6, 2003	Written Opinion
M0656.70070WO00	PCT/US01/32444	December 17, 2003	International Preliminary Examination Report

### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Liu et al., *Applicant*

By:   
Janice A. Vatland, Reg. No. 52,318  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			APPLICATION NO.: 09/982,548	ATTY. DOCKET NO.: M0656.70070US00	
			FILING DATE: October 18, 2001	CONFIRMATION NO.: 7782	
			APPLICANT: Liu et al.		
			GROUP ART UNIT: 1623	EXAMINER: McIntosh III, Traviss C	
Sheet	1	of	4		

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A53	4,551,296		Kavesh et al.	11-05-1985
	A54	4,830,013		Maxwell	05-16-1989
	A55	4,928,694		Maxwell	05-29-1990
	A56	5,453,171		Ma et al.	09-26-1995
	A57	5,569,366		Chen et al.	10-29-1996
	A58	5,607,859		Biemann et al.	03-04-1997
	A59	5,687,090		Chen et al.	11-11-1997
	A60	5,752,019		Rigoutsos et al.	05-12-1998
	A61	5,759,767		Lakowicz et al.	06-02-1998
	A62	5,767,269		Hirsh et al.	06-16-1998
	A63	5,952,653		Covey et al.	09-14-1999
	A64	5,990,097		Kennedy	11-23-1999
	A65	5,993,846		Friedman et al.	11-30-1999
	A66	6,190,875	B1	Ben-Artzi et al.	02-20-2001
	A67	6,268,146	B1	Shultz et al.	07-31-2001
	A68	6,291,439	B1	Klock	09-18-2001
	A69	6,309,853	B1	Friedman et al.	10-30-2001
	A70	6,333,051	B1	Kabanov et al.	12-25-2001
	A71	6,597,996	B1	Venkataraman et al.	07-22-2003

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B15	EP	0 114 589	B1	President and Fellows of Harvard College	09-23-1987	
	B16	EP	0 140 781		DROPIC Societe Civile de Gestion de Droit de Propriete Industrielle CHOAY	05-08-1985	Y-ABSTRACT ONLY
	B17	EP	0 244 236	A2	Novo Industri A/S	11-04-1987	
	B18	EP	0 342 215	B1	Genentech, Inc. et al.	08-25-1993	
	B19	EP	0 394 971	A1	KabiVitrum AB et al.	10-31-1990	
	B20	WO	92/01003	A1	Board of Regents, the University of Texas System	01-23-1992	
	B21	WO	93/05167	A1	Children's Medical Center Corporation	03-18-1993	
	B22	WO	93/10450	A1	Glyko, Inc.	05-27-1993	
	B23	WO	93/15406	A1	Imperial College of Science, Technology and Medecine	08-05-1993	
	B24	WO	94/12618	A1	Massachusetts Institute of Technology et al.	06-09-1994	

FORM PTO-1449/A and B (Modified)			APPLICATION NO.: 09/982,548	ATTY. DOCKET NO.: M0656.70070US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE: October 18, 2001	CONFIRMATION NO.: 7782
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Sheet	3	of	4	GROUP ART UNIT: 1623 EXAMINER: McIntosh III, Traviss C

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PATENT & TRADEMARK OFFICE  
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C67	JOHNSON et al., "Endothelial Cells Preparing to Die by Apoptosis Initiate a Program of Transcriptome and Glycome Regulation", <i>The FASEB Journal</i> , 18: 188-190, 2004.		
C68	KEISER et al., "Direct Isolation and Sequencing of Specific Protein-binding Glycosaminoglycans", <i>Nature Medicine</i> , 7(1): 123-128, 2001.		
C69	KISHIBE et al., "Structural Requirements of Heparan Sulfate for the Binding to the Tumor-derived Adhesion Factor/ Angiomodulin that Induces Cord-like Structures to ECV-304 Human Carcinoma Cells", <i>The Journal of Biological Chemistry</i> , 275(20): 15321-15329, 2000.		
C70	LECKBAND et al., "Characterization of the Active Site of Heparinase", <i>Abstracts of Papers Part I: Fourth Chemical Congress of North America</i> , 202(1): a56, 1991.		
C71	LEWIN, <i>Genes V</i> , p.13, 1994.		
C72	LIU, Dongfang, et al., "Dynamic Regulation of Tumor Growth and Metastasis by Heparan Sulfate Glycosaminoglycans", <i>Seminars in Thrombosis and Hemostasis</i> , 28(1): 67-78, 2002.		
C73	LIU, Dongfang, et al., "Tumor Cell Surface Heparan Sulfate as Cryptic Promoters or Inhibitors of Tumor Growth and Metastasis", <i>PNAS</i> , 99(2): 568-573, 2002.		
C74	LIU, Jian, et al., "Strategy for the Sequence Analysis of Heparin", <i>Glycobiology</i> , 5(8): 765-774, 1995.		
C75	LIU, Jian, et al., "Characterization of a Heparan Sulfate Octasaccharide that Binds to Herpes Simplex Virus Type 1 Glycoprotein D", <i>The Journal of Biological Chemistry</i> , 277(36): 33456-33467, 2002.		
C76	MARCIENIAK, "Differential Role of Fractionated Heparin in Antithrombin-III Proteolysis", <i>Blood</i> , 59(3): 576-581, 1982.		
C77	MCLEAN et al., "Enzymic Removal of 2-O-Sulphato- $\Delta_{4,5}$ -Glycuronic Acid Residues from Heparin Oligosaccharides", <i>Proc. of the 7th Int'l. Symposium of Glycoconjugates</i> , p.68-69, 1983.		
C78	MURPHY et al., "Basic Fibroblast Growth Factor Binding and Processing by Human Glioma Cells", <i>Molecular and Cellular Endocrinology</i> , 114: 193-203, 1995.		
C79	MYETTE et al., "The Heparin / Heparan Sulfate 2-O-Sulfatase from <i>Flavobacterium heparinum</i> ", <i>The Journal of Biological Chemistry</i> , 278(14): 12157-12166, 2003.		
C80	MYETTE et al., "Molecular Cloning of the Heparin / Heparan Sulfate $\Delta 4,5$ Unsaturated Glycuronidase from <i>Flavobacterium heparinum</i> , its Recombinant Expression in <i>Escherichia coli</i> , and Biochemical Determination of its Unique Substrate Specificity", <i>Biochemistry</i> , 41(23): 7424-7434, 2002.		
C81	MYETTE et al., "Expression in <i>Escherichia coli</i> , Purification and Kinetic Characterization of Human Heparan Sulfate 3-O-Sulfotransferase-1", <i>Biochemical and Biophysical Research Communications</i> , 290(4): 1206-1213, 2002.		
C82	NATKE et al., "Heparinase Treatment of Bovine Smooth Muscle Cells Inhibits Fibroblast Growth Factor-2 Binding to Fibroblast Growth Factor Receptor but not FGF-2 Mediated Cellular Proliferation", <i>Angiogenesis</i> , 3: 249-257, 1999.		
C83	NESHEIM et al., "Dependence of Antithrombin III and Thrombin Binding Stoichiometries and Catalytic Activity on the Molecular Weight of Affinity-purified Heparin", <i>The Journal of Biological Chemistry</i> , 261(7): 3214-3221, 1986.		
C84	PADERA et al., "FGF-2/ Fibroblast Growth Factor Receptor/ Heparin-like Glycosaminoglycan Interactions: A Compensation Model for FGF-2 Signaling", <i>The FASEB Journal</i> , 13(13): 1677-1687, 1999.		
C85	PIXLEY et al., "Preparation of Highly Stable Antithrombin-sepharose and Utilization for the Fractionation of Heparin", <i>Thrombosis Research</i> , 26(2): 129-133, 1982.		
C86	POJASEK et al., "Biochemical Characterization of the Chondroitinase B Active Site", <i>The Journal of Biological Chemistry</i> , 277(34): 31179-31186, 2002.		
C87	POJASEK et al., "Recombinant Expression, Purification, and Kinetic Characterization of Chondroitinase AC and Chondroitinase B from <i>Flavobacterium heparinum</i> ", <i>Biochemical and Biophysical Research Communications</i> , 286(2): 343-351, 2001.		
C88	RAMAN et al., "Identification of Structural Motifs and Amino Acids within the Structure of Human Heparan Sulfate 3-O-Sulfotransferase that Mediate Enzymatic Function", <i>Biochemical and Biophysical Research Communications</i> , 290(4): 1214-1219, 2002.		
C89	RAMAN et al., "The Heparin / Heparan Sulfate 2-O-Sulfatase from <i>Flavobacterium heparinum</i> : A Structural and Biochemical Study of the Enzyme Active Site and Saccharide Substrate Specificity", <i>The Journal of Biological Chemistry</i> , 278(14): 12167-12174, 2003.		

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FORM PTO-1449/A and B (Modified)

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STATEMENT BY APPLICANT**

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GROUP ART UNIT: 1623

EXAMINER: McIntosh III, Traviss C

Sheet 4 of 4

C90	RHOMBERG et al., "Mass Spectrometric Sequencing of Heparin and Heparan Sulfate Using Partial Digestion with Heparinases", <i>45<sup>th</sup> Annual Conference of Mass Spectrometry Allied Topics</i> , p.1026-1027, 1997. <b>ABSTRACT ONLY</b>	
C91	RHOMBERG et al., "Mass Spectrometric and Capillary Electrophoretic Investigation of Heparin, Heparinases, and Related Compounds", <i>MIT (Department of Chemistry)</i> , 1998. <b>THESIS</b>	
C92	RUDD et al., "Oligosaccharide Sequencing Technology", <i>Nature</i> , 388: 205-207, 1997.	
C93	SASISEKHARAN et al., "Roles of Heparan-sulphate Glycosaminoglycans in Cancer", <i>Nature Reviews</i> , 2: 521-528, 2002.	
C94	SHRIVER et al., "Emerging Views of Heparan Sulfate Glycosaminoglycan Structure / Activity Relationships Modulating Dynamic Biological Functions", <i>TCM</i> , 12(2): 71-77, 2002.	
C95	SUNDARAM et al., "Rational Design of Low-molecular Weight Heparins with Improved <i>In vivo</i> Activity", <i>PNAS</i> , 100(2): 651-656, 2003.	
C96	TAYLOR et al., "Protamine is an Inhibitor of Angiogenesis", <i>Nature</i> , 297: 307-312, 1982.	
C97	WISHART et al., "A Single Mutation Converts a Novel Phosphotyrosine Binding Domain into a Dual-specificity Phosphatase", <i>The Journal of Biological Chemistry</i> , 270(45): 26782-26785, 1995.	
C98	WITKOWSKI et al., "Conversion of a $\beta$ -Ketoacyl Synthase to a Malonyl Decarboxylase by Replacement of the Active-site Cysteine with Glutamine", <i>Biochemistry</i> , 38(36): 11643-11650, 1999.	
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C100	YAN et al., "Prime Numbers and the Amino Acid Code: Analogy in Coding Properties", <i>J. Theor. Biol.</i> , 151: 333-341, 1991.	
C101	YODER et al., "New Domain Motif: The Structure of Pectate Lyase C, a Secreted Plant Virulence Factor", <i>Science</i> , 260:1503-1506, 1993.	
C102	YODER et al., "Unusual Structural Features in the Parallel $\beta$ -helix in Pectate Lyases", <i>Structure</i> , 1(4):241-251, 1993.	
C103	ZHANG et al., "6-O-Sulfotransferase-1 Represents a Critical Enzyme in the Anticoagulant Heparan Sulfate Biosynthetic Pathway", <i>The Journal of Biological Chemistry</i> , 276(45): 42311-42321, 2001.	
C104	ZHAO et al., "Rapid, Sensitive Structure Analysis of Oligosaccharides", <i>Proc. Natl. Acad. Sci. USA</i> , 94: 1629-1633, 1997.	

EXAMINER

DATE CONSIDERED

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

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	B25	WO	95/13830	A1	Massachusetts Institute of Technology et al.	05-26-1995	
	B26	WO	96/01648	A1	Ibex Technologies R and D, Inc.	01-25-1996	
	B27	WO	97/11684	A1	Ibex Technologies, Inc.	04-03-1997	
	B28	WO	98/04902	A1	The State of Oregon	02-05-1998	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
O I P E MAR 17 2004 MADEMARK OFFICE	C47	AMEER et al., "A New Approach to Regional Heparinization: Design and Development of a Novel Immobilized Heparinase Device", <i>Blood Purification Meeting Information: The International Conference on Continuous Renal Replacement Therapies</i> , 16(2):107-108, 1998. <b>ABSTRACT ONLY</b>	
	C48	BAUMANN et al., "Three-dimensional Structure of the Alkaline Protease of <i>Pseudomonas aeruginosa</i> : A Two-domain Protein with a Calcium Binding Parallel Beta Roll Motif", <i>The EMBO Journal</i> , 12(9): 3357-3364, 1993.	
	C49	BERRY et al., "Distinct Heparan Sulfate Glycosaminoglycans are Responsible for Mediating Fibroblast Growth Factor-2 Biological Activity Through Different Fibroblast Growth Factor Receptors", <i>The FASEB Journal</i> , Express Article No.:10.1096/fj.00-0661fje: 1-19, 2001.	
	C50	BIEMANN, "Four Decades of Structure Determination by Mass Spectrometry: From Alkaloids to Heparin", <i>J. Am. Soc. Mass. Spectrom.</i> , 13: 1254-1272, 2002.	
	C51	CARLSON et al., "Behavior of Antithrombin III Isoforms on Immobilized Heparins: Evidence that the Isoforms Bind to Different Numbers of Low-affinity Heparin Sites", <i>The Journal of Biological Chemistry</i> , 263(5):2187-2194, 1988.	
	C52	CLAVERIE et al., "Information Enhancement Methods for Large Scale Sequence Analysis", <i>Computers Chem.</i> , 17(2): 191-201, 1993.	
	C53	COHEN, "The Parallel $\beta$ Helix of Pectate Lyase C: Something to Sneeze At", <i>Science</i> , 260: 1444-1445, 1993.	
	C54	CRUM et al., "A New Class of Steroids Inhibits Angiogenesis in the Presence of Heparin or a Heparin Fragment", <i>Science</i> , 230: 1375-1378, 1985.	
	C55	DULL et al., "Lung Endothelial Heparan Sulfates Mediate Cationic Peptide-induced Barrier Dysfunction: A New Role for the Glycocalyx", <i>Am. J. Physiol. Lung Cell Mol. Physiol.</i> , 285: L986-995, 2003.	
	C56	ERNST et al., "Expression in <i>Escherichia coli</i> , Purification and Characterization of Heparinase I from <i>Flavobacterium heparinum</i> ", <i>Biochem. J.</i> , 315: 589-597, 1996.	
	C57	ERNST et al., "Enzymatic Degradation of Glycosaminoglycans", <i>Critical Reviews in Biochemistry and Molecular Biology</i> , 30(5): 387-444, 1995.	
	C58	FOLKMAN et al., "Angiogenesis Inhibition and Tumor Regression Caused by Heparin or a Heparin Fragment in the Presence of Cortisone", <i>Science</i> , 221:719-725, 1983.	
	C59	FRANKLIN et al., " <i>Pseudomonas aeruginosa</i> AlgG is a Polymer Level Alginate C5-Mannuronan Epimerase", <i>Journal of Bacteriology</i> , 176(7): 1821-1830, 1994.	
	C60	GACESA, "Alginate-modifying Enzymes: A Proposed Unified Mechanism of Action for the Lyases and Epimerases", <i>FEBS Letters</i> , 212(2):199-202, 1987.	
	C61	GIOLDASSI et al., "Determination of Phosphorylated and Sulfated Linkage-region Oligosaccharides in Chondroitin / Dermatan and Heparan Sulfate Proteoglycans by High Performance Liquid Chromatography", <i>J. Liq. Chrom. &amp; Rel. Technol.</i> , 22(13): 1997-2007, 1999.	
	C62	GODAVARTI et al., "Heparinase I from <i>Flavobacterium heparinum</i> : Role of Positive Charge in Enzymatic Activity", <i>The Journal of Biological Chemistry</i> , 273(1): 248-255, 1998.	
	C63	GUERRINI et al., "A Novel Computational Approach to Integrate NMR Spectroscopy and Capillary Electrophoresis for Structure Assignment of Heparin and Heparan Sulfate Oligosaccharides", <i>Glycobiology</i> , 12(11): 713-719, 2002.	
	C64	HAYES, "Proteoteins", <i>American Scientist, the Magazine of Sigma Xi, the Scientific Research Society</i> , 86(3): 216-221, 1998.	
	C65	HIGUCHI, "Recombinant PCR", <i>PCR Protocols: A Guide to Methods and Applications</i> , Academic Press, Inc., NY: 1990, Chapter 22, 177-183.	
	C66	HORNER et al., "Heterogeneity of Rat Skin Heparin Chains with High Affinity for Antithrombin", <i>Biochem. J.</i> , 244: 693-698, 1987.	